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| 10/658,953 | 09/10/2003 | Alexander Karl Huwig | 20959/2140 (P 63469) | 3518 |

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| EXAMINER |
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FUBARA, BLESSING M

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1618

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04/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/658,953 | Applicant(s) HUWIG ET AL. | |
| | Examiner BLESSING M. FUBARA | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,17-27 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) 5-10,13 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,11,12,14,15,17-20,27 and 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 1/29/2010. Claim 1 is amended. Claim 29 is canceled. Thus, claims 1, 2 and 4-15, 17-27 and 33-43 are pending. Claims 5-10, 13 and 21-26 are withdrawn from consideration; claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27 and 33-43 are under examination.

Response to Arguments

Previous rejections/objections that are not reiterated herein are withdrawn. The objection to the specification is withdrawn in view of the amendment to the specification including a "Brief Description of the Drawings."

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27 and 33-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540) for reasons of record and with minor modification to address the amendment to claim 1 and cancellation of claim 29..

5. Hughes discloses liquid dentifrice and mouthwash compositions that comprise one or more of oral composition components that are selected from abrasives, binders such as xanthan gum and carboxymethylcellulose at 0.1-5%, humectants, surfactants, fluoride ion sources, anticalculus agents and sweeteners and additionally comprises dimethicone copolyol selected from alkyl- and alkoxy-dimethicone copolyols (abstract; column 5, lines 30-35, 52-65); may also include lipophilic flavorants and lipophilic antimicrobial compounds (column 4, lines 29-62). Silica gels or xerogels (column 6, line 10) or calcium carbonate (column 6, lines 22 and 23) are abrasive agents. The composition of Hughes may also contain surfactants (column 6, lines 34-48), soluble fluoride ions such as sodium fluoride, stannous fluoride (column 6, lines 49-55), anti-calculus agents, of which specific example is zinc compounds (column 6, line 59 to column 7 line 22), sweetening and flavoring agents at 0.005 to about 2% and humectants (column 7, lines 23-26, 43), bleaching agent (column 7, line 52 to column 8, line 45), optional agents such as dyes/colorant, pH adjusting agents, plant extracts and desensitizing agents such as potassium nitrate, and mixtures thereof (column 7, lines 27-41), and effervescent agents such as carbonate that are effective under acidic conditions and mixed with organic acids such as citric acid, malic

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acid, succinic acid and gluconic acid (column 8, lines 13-23). The composition may also contain polyethylene glycols (column 10, lines 60 and 61) and phosphonic acid chelating agents at 0.1-1% (column 12, line 16); and the composition contains from about 0-60% or 5-30% ethanol when it is a mouthwash (column 7, line 45) meeting claims 20 and 42. The xanthan gum and polyethylene glycol meet the limitation of polymer in claims 1, 12 and 36. The presence of phosphonic acid, citric acid meets the acid requirements of claims 1, 4, 11, 34 and 35. The fluoride ions meet the requirements of claims 14 and 37; potassium nitrate is a source of potassium ion meeting claims 15 and 38; carboxymethylcellulose meets the film-forming agent of claim 1; the sweetening agent at 0.005 to about 2% meets claims 19 and 41. Applying the composition containing desensitizing agent meets claim 27 and the composition of Hughes meets claims 18 and 40. The solubility of the acid recited in claims 2 and 33 is a property of the acid so that the acid of Hughes, which is the same phosphonic acid as in the claims, would have those properties and thus meet claims 2 and 33. Regarding claims 17 and 39, one film-forming agent may replace another without negatively affecting the composition. In this case, hydroxypropyl cellulose could be substituted for carboxymethyl cellulose with the expectation that the composition would be effective as a dentifrice.

6. Hughes discloses the claimed composition as described above. The difference between the Hughes composition and the claimed composition is that while Hughes teaches that the composition can be acidic, Hughes does not specifically teach a pH of from 1.5 to 3.5.

However, Asano describes dentifrice composition containing fluoride ion from potassium of sodium fluoride at 0.0025 to 4%, zinc ions, polyethylene glycol, hydroxyl ethyl cellulose, silica abrasive, xanthan gum or carrageenan at 0.2 to 5%, humectants, succinic acid or gluconic acid or

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maleic acid or fumaric acid as buffering agents; 0.01 to 2% flavoring agent/sweetening; ethanol/water solvent; Asano specifically teaches that the pH of the composition should be maintained at acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). For claim 43, the artisan has the skills to adjust the pH of the composition to a value in which the fluoride ions are maintained in solution. Thus, when Hughes in view of Asano are taken together, the ordinary skilled artisan would have been motivated to maintain the pH of the composition at acidic pH in order that the fluoride can be maintained in solution as a low pH is expected to maintain the fluoride and zinc ions in solution.

Response to Arguments

1. Applicant's arguments filed 1/29/2010 have been fully considered but they are not persuasive.
2. Applicant states that the examiner "completely" ignored the fact that Hughes clearly distinguishes toothpastes, denture cleansing liquid and pastes and that each of the components listed is not compatible with each type of composition.
3. Response: The examiner did not ignore any disclosure in Hughes. Rather, the examiner considered the Hughes reference as a whole. Column 5, lines 28 and 29 read as follows:
4. "Compositions in the form of toothpastes, denture cleansing liquids and pastes and the like will generally comprise a binder or thickening agent." These lines do not say that each of the listed components is not compatible with each of the compositions.

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5. Applicant further argues that the denture cleanser additionally comprises effervescent generators according to column 7, lines 47-50.

6. Response: Column 7, lines 47-50 reproduced below:

7. “Denture cleanser compositions of the invention can additionally include one or more bleaching agents, organic peroxyacid precursors, effervescence generators, chelating agents, etc” does not say that says that the components listed for the composition in Hughes are not compatible with each of the compositions. In fact, in a preceding section at column 5, lines 52, 53 and lines 47-50 identifies denture cleansing compositions as liquids.

8. Applicant then argues that effervescent generators contain alkali metal carbonate or bicarbonate in “admixture” with organic acids as disclosed in Hughes at column 8, lines 13-23; that upon contact with water, the carbonate or bicarbonate reacts with the acid and carbon dioxide is released; and that applicant has explained previously explained that effervescence generators can only be used in solid compositions and that in Hughes acids are disclosed “only” as component of the effervescence generators and that effervescent generators are typically used as disintegration agents in tablets. Applicant cites Remington, the Science and Practice of Pharmacy, 21st edition at page 718, right column, under oral powders, and starting at “effervescent granules” and ending at “acid-base reaction.” In addition applicant has cited page 890 of the Remington, the paragraph bridging left and right column; and finally cited first paragraph of the right column of the Remington, all in an attempt to support the notion that effervescent generators such as the alkali metal carbonates and bicarbonates are used only in solid compositions.

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9. Response: The examiner disagrees and the paragraph in Hughes cited by applicant and reproduced below: (column 8, lines 13-33)

10. “The effervescence generator can be selected from generators which are effective under acid, neutral or alkaline pH conditions, but preferably it consists of a combination of a generator which is effective or most effective under acid or neutral pH conditions and a generator which is effective or most effective under alkaline pH conditions. Effervescence generators which are effective under acid or neutral pH conditions include a combination of at least one alkali metal carbonate or bicarbonate, such as sodium bicarbonate, sodium carbonate, sodium sesquicarbonate, potassium carbonate, potassium bicarbonate, or mixtures thereof, in admixture with at least one non-toxic, physiologically-acceptable organic acid, such as tartaric, fumaric, citric, malic, maleic, gluconic, succinic, salicylic, adipic or sulphamic acid, sodium fumarate, sodium or potassium acid phosphates, betaine hydrochloride or mixtures thereof. Of these, malic acid is preferred. Effervescence generators which are effective under alkaline pH conditions include persalts such as alkali and alkaline earth metal peroxoborates as well as perborates, persulphates, percarbonates, perphosphates and mixtures thereof as previously described, for example, a mixture of an alkali metal perborate (anhydrous, mono- or tetrahydrate) with a monopersulphate such as CAROAT marketed by E I du Point de Nemours Co. and which is a 2:1:1 mixture of monopersulphate, potassium sulphate and potassium bisulphate and which has an active oxygen content of about 4.5%.”

11. Hughes does not say that the acids are only used in tablets. Hughes does not say that effervescent generators are only used in tablets. Hughes in lines 4 and 5 discloses denture cleansing compositions to also include effervescent generator and there is no disclosure where the denture cleansing composition is only a solid. In fact in column 5, lines 28, 29, 52 and 53, Hughes has specifically identified the denture cleansing compositions as liquids. Therefore, although, Hughes in column 8, lines 34 and 35 discloses a preferred denture cleansing composition as a tablet, Hughes is not limited to the preferred embodiments and especially for the fact that Hughes had prior to the above section identified the denture cleansing composition as a liquid.

12. The examiner therefore, disagrees agrees with the applicant that effervescent generators are only present in solid compositions. The sections of Remington cited by applicant is specific

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to effervescent tablets and these section or any other sections of the Remington does not say that effervescent generators are only in tablet formulations. The examiner further notes that carbonated beverages effervesce when the beverage is opened and if tipped or shaken before opening violently effervesce, and carbonated beverages are liquids. The Remington text book does not confirm that components of effervescence generators are only present in solid compositions.

13. Applicant argues that claim 1 is amended to recite a pH of 2-3 and that Asano does not suggest to use a pH of below 3.5 and that the examples in Hughes has pH values of 4.0 to 5.5.

14. The examiner agrees that Asano does not teach a pH of 3 or 2-3. However, Asano suggests that low pH is necessary to maintain the fluoride in solution so that the artisan would be motivated to keep the pH low in order to maintain the fluoride in solution. Thus, the motivation is to keep the fluoride in solution and as such, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the having a fluoride in solution in a liquid composition at a low pH is not of innovation but of ordinary skill and common sense.

15. Applicant also refers to the declaration by Carlo Bolis. But the declaration had been previously addressed and the response to the declaration presented in the office action of 9/30/09 is incorporated here and reproduced below:

16. Declaration under 37 CFR 1.132 by Carlo Bolis:

17. *Applicant argues on pages 10 and 11 of the remarks that the claimed composition is used to form massive plugs deep in the dentinal tubules to desensitize the tooth as demonstrated in applicant's specification at page 20, lines 1-8 and 17-23. But this demonstration on page 20,*

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lines 1-8 and 17-23 has not compared the claimed composition with the composition of the prior art and the composition used in the plugging experiment is not claimed.

18. Applicant also refers to Example 5 and 8 having first component of phosphonic acid and a second component of polymer comprising polyacrylic acid and polyethylene glycol, hydroxypropyl cellulose and ethanol/water component. But while the composition of Example 5 is a specific composition that has not been claimed, applicant has not also compared the composition in Example 5 with the composition of the cited prior art. While Also, Example 8 studies the effect of desensitization of the specific composition of Example 5, the composition in the Example 5 is not the claimed composition and Example 8 does not compare the composition in Example 5 with the composition of the cited prior art.

19. Applicant refers to the declaration by Carlo Bolis as demonstrating that the pH of the composition of Example 8 prepared in accordance with the procedure of Example 5 has a pH of 2.7, which is within the claimed range of 1.5 to 3.5. But, a) a pH of 2.7 is but one point and representing the pH of one specific composition that is not the claimed composition (see claim 1), b) the rejection was not that claim 1 cannot have a pH range of 1.5 to 3.5, c) applicant has not compared the composition having a pH of 2.7 with the composition of the cited prior art.

20. The declaration under 37 CFR 1.132 filed 7/21/09 is insufficient to overcome the rejection of claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, 29 and 33-43 based upon 35 USC 103 over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540) as set forth in the last Office action and reiterated herein and modified to address new claims 33-43 because: the composition used in the determination of the pH is not commensurate in scope with the claims

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and there is also no comparison with the composition of the prior art and the declaration is silent on the composition of the prior art.

21. The composition of Hughes is also a liquid, which is also applied to teeth

22. No claim is allowed.

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618